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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2432

of 16 September 2024

granting a Union authorisation for the biocidal product family ‘Diversey Hydrogen Peroxide Product Family’ in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

(OJ L 2432, 17.9.2024, p. 1)

Amended by:

Official Journal			
	No	page	date
► <u>M1</u>	Commission Implementing Regulation (EU) 2026/1159 of 28 May 2026	L 1159	1 29.5.2026

**COMMISSION IMPLEMENTING REGULATION (EU) 2024/2432****of 16 September 2024****granting a Union authorisation for the biocidal product family
‘Diversey Hydrogen Peroxide Product Family’ in accordance with
Regulation (EU) No 528/2012 of the European Parliament and of
the Council****(Text with EEA relevance)***Article 1*

A Union authorisation with authorisation number EU-0029435-0000 is hereby granted to Diversey Europe Operations B.V for the making available on the market and use of the same biocidal product family ‘Diversey Hydrogen Peroxide Product Family’ in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 7 October 2024 until 31 October 2033.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

▼ **M1**

ANNEX

Summary of product characteristics for a biocidal product family

Diversey Hydrogen Peroxide Product Family

Product type(s)

PT04: Food and feed area

Authorisation number EU-0029435-0000

R4BP asset number EU-0029435-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	Diversey Hydrogen Peroxide Product Family
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1.2. Product type(s)

Product type(s)	PT04: Food and feed area
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1.3. Authorisation holder

Name and address of the authorisation holder	Name	Diversey Europe Operations B.V.
	Address	De Corridor 4 (Regulatory team) 3621 ZB Breukelen NL
Authorisation number	EU-0029435-0000	
<i>R4BP asset number</i>	EU-0029435-0000	
Date of the authorisation	7 October 2024	
Expiry date of the authorisation	31 October 2033	

1.4. Manufacturer(s) of the product

Name of manufacturer	Diversey Europe Operations B.V.
Address of manufacturer	De Corridor 4 (Regulatory team) 3621 ZB Breukelen Netherlands (the)
Location of manufacturing sites	Diversey Europe Operations B.V. site 1 Strada Statale 235 26010 Bagnolo Cremasco (CR) Italy Diversey Europe Operations B.V. site 2 Rembrandtlaan 414 7545 ZW Enschede Netherlands (the) Diversey Europe Operations B.V. site 3 Cotes Park Industrial Estate DE55 4PA Somercotes Alfreton United Kingdom of Great Britain and Northern Ireland (the) Diversey Europe Operations B.V. site 4 Avenida Conde Duque 5, 7 y 9 ; Poligono Industrial La Postura 28343 Valdemoro (Madrid) Spain Diversey Europe Operations B.V. site 5 Morschheimer Strasse 12 67292 Kirchheimbolanden Germany

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Name of manufacturer	Evonik Antwerpen NV
Address of manufacturer	Tijsmanstunnel West 2040 Antwerpen Belgium
Location of manufacturing sites	Evonik Antwerpen NV site 1 Tijsmanstunnel West 2040 Antwerpen Belgium
Name of manufacturer	Evonik Operations GmbH
Address of manufacturer	Rellinghauser Straße 1-11 45128 Essen Germany
Location of manufacturing sites	Evonik Operations GmbH site 1 Untere Kanalstr. 3 79618 Rheinfelden Germany
Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1 9721 Weißenstein Austria
Location of manufacturing sites	Evonik Peroxid GmbH site 1 Industriestraße 1 9721 Weißenstein Austria
Name of manufacturer	Evonik Peroxide Netherlands BV
Address of manufacturer	Hettenheuvelweg 37 /39 1101 BM Amsterdam Netherlands (the)
Location of manufacturing sites	Evonik Peroxide Netherlands BV site 1 Oosterhorn 14 9936 HD Farmsum Netherlands (the)
Name of manufacturer	ELETTROCHIMICA VALLE STAFFORA SPA
Address of manufacturer	VIA TORTONA 73 27055 Rivanazzano Italy
Location of manufacturing sites	ELETTROCHIMICA VALLE STAFFORA SPA site 1 VIA TORTONA 73 27055 Rivanazzano Italy
Name of manufacturer	Brenntag SA
Address of manufacturer	Zone d'Activités les Sauzets 07340 Andance France
Location of manufacturing sites	Brenntag SA site 1 Zone d'Activités les Sauzets 07340 Andance France Brenntag SA site 2 12 sente des Jumelles 76710 Montville France
Name of manufacturer	CHEPORT, spol. s r.o.
Address of manufacturer	Lhotsko 93 763 12 Vizovice Czechia
Location of manufacturing sites	CHEPORT, spol. s r.o. site 1 Lhotsko 93 763 12 Vizovice Czechia

▼ **M1**

Name of manufacturer	Brenntag Polska Sp. z o.o
Address of manufacturer	Ul. Towarowa 6 05-530 Góra Kalwaria Poland
Location of manufacturing sites	Brenntag Polska Sp. z o.o site 1 Ul. Towarowa 6 05-530 Góra Kalwaria Poland
Name of manufacturer	Evonik Peroxide Spain, S.L.U.
Address of manufacturer	C/ Afueras s/n. 50784 La Zaida Spain
Location of manufacturing sites	Evonik Peroxide Spain, S.L.U. site 1 C/ Afueras s/n. 50784 La Zaida Spain
Name of manufacturer	Solenis Sweden AB
Address of manufacturer	Högastensgatan 18 S-25232 Helsingborg Sweden
Location of manufacturing sites	Solenis Sweden AB Högastensgatan 18 S-25232 Helsingborg Sweden
Name of manufacturer	Solenis Germany GmbH & Co. KG
Address of manufacturer	Füttingsweg 20 D-47508 Krefeld Germany
Location of manufacturing sites	Solenis Germany GmbH & Co. KG Füttingsweg 20 D-47508 Krefeld Germany
Name of manufacturer	Solenis Finland Oy
Address of manufacturer	Kolmihaarankatu 7 FIN-33330 Tampere Finland
Location of manufacturing sites	Solenis Finland Oy Kolmihaarankatu 7 FIN-33330 Tampere Finland

1.5. **Manufacturer(s) of the active substance(s)**

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Antwerpen NV
Address of manufacturer	Tijlmanstunnel West 2040 Antwerpen Belgium
Location of manufacturing sites	Evonik Antwerpen NV site 1 Tijlmanstunnel West 2040 Antwerpen Belgium
Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Operation GmbH
Address of manufacturer	Rellinghauser Straße 1-11 45128 Essen Germany
Location of manufacturing sites	Evonik Operation GmbH site 1 Untere Kanalstr. 3 79618 Rheinfelden Germany

▼ **M1**

Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Peroxid GmbH
Address of manufacturer	Industriestraße 1 9721 Weißenstein Austria
Location of manufacturing sites	Evonik Peroxid GmbH site 1 Industriestraße 1 9721 Weißenstein Austria
Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Peroxide Netherlands BV
Address of manufacturer	Hettenheuvelweg 37 /39 1101 BM Amsterdam Netherlands (the)
Location of manufacturing sites	Evonik Peroxide Netherlands BV site 1 Oosterhorn 14 9936 HD Farmsum Netherlands (the)
Active substance	Hydrogen peroxide
Name of manufacturer	Evonik Peroxide Spain, S.L.U.
Address of manufacturer	C/ Afueras s/n. 50784 La Zaida Spain
Location of manufacturing sites	Evonik Peroxide Spain, S.L.U. site 1 C/ Afueras s/ n. 50784 La Zaida Spain

2. **PRODUCT FAMILY COMPOSITION AND FORMULATION**

2.1. **Qualitative and quantitative information on the composition of the family**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 - 49,9 % (w/w)

2.2. **Type(s) of formulation**

Formulation type(s)	SL Soluble concentrate
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PART II

SECOND INFORMATION LEVEL META SPC(S)

1. **META SPC 1 ADMINISTRATIVE INFORMATION**

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC: META Divosan Spray
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1.2. **Suffix to the authorisation number**

Number	1-1
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▼M1**1.3. Product type(s)**

Product type(s)	PT04: Food and feed area
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2. META SPC 1 COMPOSITION**2.1. Qualitative and quantitative information on the composition of the meta SPC 1**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 - 49,9 % (w/w)

2.2. Type(s) of formulation of the meta SPC 1

Formulation type(s)	SL Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects. H272: May intensify fire; oxidiser.
Precautionary statements	P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P273: Avoid release to the environment. P280: Wear protective gloves / eye protection / face protection.. P301+P312: IF SWALLOWED: Call a POISON CENTER / doctor / physician if you feel unwell. P330: Rinse mouth. P302+P352: IF ON SKIN: Wash with plenty of water/ soap. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/ doctor/physician if you feel unwell. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER / doctor.

▼ **M1**

P332+P313: If skin irritation occurs: Get medical advice.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P405: Store locked up.
P501: Dispose of contents in accordance with local requirements.
P501: Dispose of container in accordance with local requirements.
P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P220: Keep away from clothing or other combustible materials.
P370+P378: In case of fire: Use water to extinguish.

4. **AUTHORISED USE(S) OF THE META SPC**

4.1. **Use description**

Table 1

Aseptic packaging in food and feed industries

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: Bacterial spores Development stage: Bacterial spores
Field(s) of use	indoor use Disinfection of food packaging material in closed aseptic packaging systems by sprayed or nebulised product.
Application method(s)	Method: Nebulising Detailed description: Automated spraying or nebulising in closed systems.
Application rate(s) and frequency	Application Rate: In-use concentration: 35% (w/w) hydrogen peroxide. Product concentration in hot air: 10,83 g/kg For disinfection of bacteria, yeasts and bacterial spores the product should be diluted to 35% (w/w) hydrogen peroxide. For example, for a product containing 49,9% (w/w) hydrogen peroxide: add 700 ml product to 357 ml water to achieve a dilution of 35% (w/w) hydrogen peroxide. Number and timing of application: Automated chemo-thermal disinfectant processes. Temperature: ≥ 100 °C Contact time: at least 5,5 seconds

▼ **M1**

Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

4.1.1. *Use-specific instructions for use*

The aseptic filling systems are based on the principle of aseptically forming a tube from a sterilised sheet of package material, which is continuously filled with commercially sterile liquid food product and subsequently transversally sealed to form pouches, which in turn are folded into the final package shape. The packaging material are delivered to the aseptic filling machine either in the form of (sheet) reels or in the form of pre-formed packs, tubs and bottles. Then, 35% (w/w) hydrogen peroxide is sprayed or nebulised to the packaging material gradually via a nozzle. After that, several stages follow to evaporate any excess hydrogen peroxide with sterile hot air.

Depending on the size of the receptacle, an amount of 0,1 - 1 mL of 35 % (w/w) hydrogen peroxide is sprayed or nebulised gradually via a nozzle.

Temperature: $\geq 100\text{ }^{\circ}\text{C}$

Contact time: at least 5,5 seconds.

For example, for a product containing 49,9% (w/w) hydrogen peroxide; add 700 ml product to 357 ml water to achieve a dilution of 35% (w/w) hydrogen peroxide.

The user shall always carry out a microbiological validation of the disinfection, after which a protocol for disinfection of this packaging / system can be made and used thereafter.

4.1.2. *Use-specific risk mitigation measures*

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal products, chemical resistant gloves classified under European Standard EN 374 or equivalent, face shield and RPE (APF = 10) when handling concentrated solutions during mixing and loading; chemical resistant gloves classified under European Standard EN 374 or equivalent, protective clothing chemically resistant to the biocidal products, and chemical resistant goggles consistent with European Standard EN 16321 or equivalent face shield during application. During maintenance work, wear chemical resistant gloves classified under EN 374 or equivalent, protective clothing chemically resistant to the biocidal products, chemical resistant goggles consistent with EN 16321 or equivalent face shield and RPE (APF=4) and spray water for approximately 10 seconds before opening the machine. The instructions for use of the re-filling station specify that the loading operations must take place in a cool and ventilated place. Gloves and coverall material to be specified by the authorisation holder within the product information. Observe label instructions. See section 6 for the full titles of the EN standards.

▼ M1

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC .

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

4.2. **Use description**

Table 2

Disinfection of distribution system for drinking water by cleaning in place (CIP)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: fungi Development stage: no data
Field(s) of use	indoor use Disinfection of distributing and storing installations for drinking water
Application method(s)	Method: CIP (Cleaning in place) Detailed description: Disinfecting the interior surfaces of closed systems by CIP
Application rate(s) and frequency	Application Rate: 4,7% (w/w) hydrogen peroxide. For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, in case of a 35%(w/w) hydrogen peroxide product: add 114 ml product to 819 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 3 hours Frequency: Daily / if required Temperature: room temperature

▼ **M1**

Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

4.2.1. *Use-specific instructions for use*

CIP (Cleaning in place): Clean before disinfection (Remove all deposits and dirt by a pre-flush or pre-scrape, and when necessary, a pre-soak treatment). Circulate the diluted product through the system under conditions of increased turbulence and flow velocity. After 3 hours contact time, pipelines and tanks are rinsed with water before refilled with drinking water. For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide: add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

4.2.2. *Use-specific risk mitigation measures*

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent/face shield, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent. and RPE (APF = 10) during mixing and loading. Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC .

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 air changes per hour (ACH)). Observe label instructions.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use

▼ **M1**

4.3. Use description

Table 3

Disinfection of non-porous hard surfaces and equipment by immersion

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: fungi Development stage: no data
Field(s) of use	indoor use Equipment in both food and drink industries, large scale catering kitchens and large scale canteens.
Application method(s)	Method: open system: immersion Detailed description: Manual immersion of equipment in closed baths. Automated immersion of equipment in closed baths.
Application rate(s) and frequency	Application Rate: 8,1% (w/w) hydrogen peroxide. For disinfection of bacteria, yeasts and fungi the product should be diluted to 8,1% (w/w) hydrogen peroxide. For example, in case of a 35%(w/w) hydrogen peroxide product: add 200 ml product to 738 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: 60 minutes Frequency: Daily / if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

4.3.1. Use-specific instructions for use

For disinfection of bacteria yeasts and fungi the product should be diluted to 8,1% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide; add 200 ml product to 738 ml water to achieve a dilution of 8,1% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

Immersion: Equipment in the food and feed industry is disinfected by immersion. Pre-clean the equipment. The disinfection solution should be diluted into vats (i.e. pouring or pumping the product into vats). The equipment to be disinfected is manually or automatically placed into these vats (closed baths) and taken out after a contact time of not less than 60 minutes. After the disinfection procedure is completed, equipment is rinsed with water. The disinfection solution in the immersion/dipping bath should be replaced after each disinfection cycle.

▼ M1

4.3.2. *Use-specific risk mitigation measures*

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent, face shield and RPE (APF = 10) during mixing and loading and application. Gloves and coverall material to be specified by the authorisation holder within the product information. No access of other worker to the room is permitted during disinfection without wearing adequate PPE and RPE as described above. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH). Dipping bath has to be placed in a separated room. For use only in areas inaccessible to the general public. Professional users without PPE and RPE (APF=10) are not allowed to enter the disinfection room. Keep the bath closed during disinfection, only open to load and discharge.

Observe label instructions.

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

4.4. Use description

Table 4

Disinfection of surfaces by cleaning in place (CIP)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: fungi Development stage: no data

▼ **M1**

Field(s) of use	indoor use Disinfection of food contact inner surfaces of pipe work and tank systems in food and feed industry
Application method(s)	Method: Cleaning in Place (CIP) Detailed description: Disinfecting the interior surfaces of closed systems by Cleaning In Place (CIP).
Application rate(s) and frequency	Application Rate: 4,7% (w/w) hydrogen peroxide. For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, in case of a 35%(w/w) hydrogen peroxide product: add 114 ml product to 819 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 3 hours Frequency: Daily / if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

4.4.1. *Use-specific instructions for use*

Clean prior to disinfection. The inner surfaces of pipe work and tank systems are disinfected by CIP process. For disinfection of bacteria yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide; add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

The process is carried out by circulating the disinfection solution through the system under conditions of increased turbulence and flow velocity. The application is automated and a closed process. After 3 hours contact time, pipelines and tanks are rinsed with water under closed system conditions as well.

4.4.2. *Use-specific risk mitigation measures*

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent/face shield, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent and RPE (APF = 10) during mixing and loading. Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

▼ M1

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH). Observe label instructions.

4.4.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

4.4.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

4.4.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 1

5.1. Instructions for use

See use specific instructions for each use.

5.2. Risk mitigation measures

See use specific risk mitigation measures for each use.

Observe label instructions.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid instructions

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

▼ M1

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

Accidental release measures

Large spillage: Collect product in suitable containers (for example made of plastic) using appropriate equipment (for example liquid pump) for disposal. Never return spills in original containers for re-use. Keep away from flammable and incompatible substances. Rinse away any residue with plenty of water. Dispose of absorbed material in accordance with the applicable environmental regulations.

Small spillage: Dilute product with lots of water and rinse away or absorb with liquid-binding material (for example diatomaceous earth or universal binder). Pick up mechanically and collect in suitable containers. Clean contaminated surface thoroughly. Pack and label wastes like the product. Do not detach label from the delivery containers prior to disposal.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer depending on local requirements.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage***Advice on protection against fire and explosion:***

Store away from direct sunlight and heat sources.

Store away from sources of ignition - No smoking.

Store away from flammable substances.

Store away from incompatible substances.

Storage:

Temperature requirement- during storage maximum 40 °C and protect from frost.

Store in clean, dry and well-ventilated places.

Transport and store container in upright position only.

Always close container tightly after removal of product.

Avoid leakage and residues of the product on the containers.

Advice on common storage:

Do not store together with alkalis, reductants, metallic salts (risk of decomposition).

Do not store together with organic solvents (risk of explosion).

Shelf-life:

24 months

6. OTHER INFORMATION

The full titles of the EN standards referenced in the 'Use-specific mitigation measures' sections are:

▼M1

EN 16321 - Eye and face protection for occupational users

EN 374 – Protective gloves against chemicals and micro-organisms

The Council Directive referenced in the ‘Use-specific mitigation measures’ sections is: Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998[RMJ1] , p.11).

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)		Divosan HS 35 VT68		Market area: EU	
		Divosan HS 35		Market area: EU	
Authorisation number		EU-0029435-0001 1-1			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 % (w/w)

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

Identifier	Meta SPC: META Divosan Bath
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1.2. Suffix to the authorisation number

Number	1-2
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1.3. Product type(s)

Product type(s)	PT04: Food and feed area
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2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 - 49,9 % (w/w)

▼ M1**2.2. Type(s) of formulation of the meta SPC 2**

Formulation type(s)	SL Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects. H272: May intensify fire; oxidiser.
Precautionary statements	P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P273: Avoid release to the environment. P280: Wear protective gloves / eye protection / face protection.. P301+P312: IF SWALLOWED: Call a POISON CENTER / doctor / physician if you feel unwell. P330: Rinse mouth. P302+P352: IF ON SKIN: Wash with plenty of water/ soap. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor/physician if you feel unwell. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER/doctor. P332+P313: If skin irritation occurs: Get medical advice. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents in accordance with local requirements. P501: Dispose of container in accordance with local requirements. P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P220: Keep away from clothing or other combustible materials. P370+P378: In case of fire: Use water to extinguish.

▼ **M1**4. **AUTHORISED USE(S) OF THE META SPC**4.1. **Use description**

Table 1

Aseptic packaging in food and feed industries

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: Bacterial spores Development stage: no data
Field(s) of use	indoor use Disinfection of food and feed packaging material in closed aseptic packaging systems by dipping, spraying or nebulising
Application method(s)	Method: Dipping, nebulising and spraying Detailed description: Automated dipping in closed systems Automated nebulising and spraying in closed systems
Application rate(s) and frequency	Application Rate: In-use concentration: 35% (w/w) hydrogen peroxide. For disinfection of bacteria, yeasts and bacterial spores, the product should be diluted to 35 % (w/w) hydrogen peroxide. For example, for a product containing 49,9 % (w/w) hydrogen peroxide; add 700 ml product to 357 ml water to achieve a dilution of 35 % (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: automated chemo-thermal disinfection processes. In-use concentration: 35% (w/w) hydrogen peroxide Spraying or nebulizing: Temperature: $\geq 100^{\circ}\text{C}$ Contact time: at least 5,5 seconds Dipping: Temperature: $\geq 80^{\circ}\text{C}$ Contact time: at least 2,5 seconds
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

▼ M1**4.1.1. Use-specific instructions for use**

The aseptic filling systems are based on the principle of aseptically forming a tube from a sterilised sheet of package material, which is continuously filled with commercially sterile liquid food product and subsequently transversally sealed to form pouches, which in turn are folded into the final package shape. The packaging material are delivered to the aseptic filling machine either in the form of (sheet) reels or in the form of pre-formed packs, tubs and bottles. The packaging material in the form of (sheet) reels passes through a deep bath filled with 35 % (w/w) hydrogen peroxide by dipping. The pre-formed packs, tubs and bottles are sprayed or fogged with 35% (w/w) hydrogen peroxide stepwise via a nozzle. After that, several stages follow to evaporate any excess hydrogen peroxide with sterile hot air.

Depending on the size of the receptacle, an amount of 0,1 - 1 mL of 35 % (w/w) hydrogen peroxide is sprayed or nebulized gradually via a nozzle.

Temperature: $\geq 100^{\circ}\text{C}$

Contact time: at least 5,5 seconds

The packaging material in the form of (sheet) reels passes through a deep bath filled with 35 % (w/w) hydrogen peroxide by dipping.

Temperature: $\geq 80^{\circ}\text{C}$

Contact time: at least 2,5 seconds

For example, for a product containing 49,9% (w/w) hydrogen peroxide; add 700 ml product to 357 ml water to achieve a dilution of 35% (w/w) hydrogen peroxide.

The user shall always carry out a microbiological validation of the disinfection, after which a protocol for disinfection of this packaging / system can be made and used thereafter.

4.1.2. Use-specific risk mitigation measures

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal products, chemical resistant gloves classified under European Standard EN 374 or equivalent, face shield and RPE (APF = 10) when handling concentrated solutions during mixing and loading; chemical resistant gloves classified under European Standard EN 374 or equivalent, protective clothing chemically resistant to the biocidal products, and chemical resistant goggles consistent with European Standard EN 16321 or equivalent face shield during application. During maintenance work, wear chemical resistant gloves classified under EN 374 or equivalent, protective clothing chemically resistant to the biocidal products, chemical resistant goggles consistent with EN 16321 or equivalent face shield and RPE (APF=4) and spray water for approximately 10 seconds before opening the machine. The instructions for use of the re-filling station specify that the loading operations must take place in a cool and ventilated place. Gloves and coverall material to be specified by the authorisation holder within the product information. Observe label instructions. See section 6 for the full titles of the EN standards.

▼ **M1**

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

The instructions for use of the re-filling station specify that the loading operations must take place in a cool and ventilated place. Observe label instructions.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

4.2. **Use description**

Table 2

Disinfection of distribution system for drinking water by cleaning in place (CIP)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: fungi Development stage: no data
Field(s) of use	indoor use Cleaning and disinfection of distributing and storing installations for drinking water
Application method(s)	Method: CIP (Cleaning in place) Detailed description: Disinfecting the interior surfaces of closed systems by CIP
Application rate(s) and frequency	Application Rate: 4,7% (w/w) hydrogen peroxide For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, in case of a 35%(w/w) hydrogen peroxide product: add 114 ml product to 819 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 3 hours Frequency: Daily / if required Temperature: room temperature

▼ **M1**

Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

4.2.1. *Use-specific instructions for use*

CIP (Cleaning in place): Clean prior to disinfection. Circulate the diluted product through the system under conditions of increased turbulence and flow velocity. After 3 hours contact time, pipelines and tanks are rinsed with water before refilled with drinking water. For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide: add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

4.2.2. *Use-specific risk mitigation measures*

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent/face shield, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent and RPE (APF = 10) during mixing and loading. Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH). Observe label instructions. Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

▼ **M1**

4.3. Use description

Table 3

Disinfection of non-porous hard surfaces and equipment by immersion

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: fungi Development stage: no data
Field(s) of use	indoor use Equipment in both food and drink industries, large scale catering kitchens and large scale canteens.
Application method(s)	Method: open system: immersion Detailed description: Manual immersion of equipment in closed baths. Automated immersion of equipment in closed baths.
Application rate(s) and frequency	Application Rate: 8,1% (w/w) hydrogen peroxide. For disinfection of bacteria, yeasts and fungi the product should be diluted to 8,1% (w/w) hydrogen peroxide. For example, in case of a 35%(w/w) hydrogen peroxide product: add 200 ml product to 738 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 60 mininutes Frequency: Daily / if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

4.3.1. Use-specific instructions for use

For disinfection of bacteria yeasts and fungi the product should be diluted to 8,1% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide: add 200 ml product to 738 ml water to achieve a dilution of 8,1% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

▼ M1

Immersion: Equipment in the food and feed industry is disinfected by immersion. Pre-clean the equipment. The disinfection solution should be diluted into vats (i.e. pouring or pumping the product into vats). The equipment to be disinfected is manually or automatically placed into these vats (closed baths) and taken out after a contact time of at least 60 minutes. After the disinfection procedure is completed, equipment is rinsed with water. The disinfection solution in the immersion/dipping bath should be replaced after each disinfection cycle.

4.3.2. *Use-specific risk mitigation measures*

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent/face shield, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent and RPE (APF = 10) during mixing and loading and application. Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

No access of other worker to the room is permitted during disinfection without wearing adequate PPE and RPE as described above.

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH).

Dipping bath has to be placed in a separate room. For use only in areas inaccessible to the general public. Professional users without PPE and RPE (APF=10) are not allowed to enter the disinfection room. Keep the bath closed during disinfection, only open to load and discharge.

Observe label instructions.

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

4.4. Use description

Table 4

Disinfection of surfaces by cleaning in place (CIP)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-

▼ **M1**

Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: fungi Development stage: no data
Field(s) of use	indoor use Disinfection of food contact inner surfaces of pipe work and tank systems in food and feed industry
Application method(s)	Method: Cleaning in Place (CIP) Detailed description: Disinfecting the interior surfaces of closed systems by Cleaning In Place (CIP).
Application rate(s) and frequency	Application Rate: 4,7% (w/w) hydrogen peroxide. For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, in case of a 35%(w/w) hydrogen peroxide product: add 114 ml product to 819 ml water. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 3 hours Frequency: Daily / if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

4.4.1. *Use-specific instructions for use*

Clean prior to disinfection. For disinfection of bacteria yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide; add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

The process is carried out by circulating the disinfection solution through the system under conditions of increased turbulence and flow velocity. The application is automated and a closed process. After 3 hours contact time, pipelines and tanks are rinsed with water under closed system conditions as well.

▼ M1**4.4.2. Use-specific risk mitigation measures**

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent, face shield and RPE (APF = 10) during mixing and loading. Gloves and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH).

Observe label instructions.

4.4.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

4.4.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

4.4.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 2**5.1. Instructions for use**

See use specific instructions for each use.

5.2. Risk mitigation measures

See use specific risk mitigation measures for each use.

Observe label instructions.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment***First aid instructions***

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor

▼ M1

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

Accidental release measures

Large spillage: Collect product in suitable containers (e.g. made of plastic) using appropriate equipment (e.g. liquid pump) for disposal. Never return spills in original containers for re-use. Keep away from flammable and incompatible substances. Rinse away any residue with plenty of water. Dispose of absorbed material in accordance with the applicable environmental regulations.

Small spillage: Dilute product with lots of water and rinse away or absorb with liquid-binding material (e.g. diatomaceous earth or universal binder). Pick up mechanically and collect in suitable containers. Clean contaminated surface thoroughly. Pack and label wastes like the product. Do not detach label from the delivery containers prior to disposal

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose of unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer depending on local requirements.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage***Advice on protection against fire and explosion:***

Store away from direct sunlight and heat sources.

Store away from sources of ignition - No smoking.

Store away from flammable substances.

Store away from incompatible substances.

Storage:

Temperature requirement- during storage maximum 40 °C and protect from frost.

Store in clean, dry and well-ventilated places.

Transport and store container in upright position only.

Always close container tightly after removal of product.

Avoid leakage and residues of the product on the containers.

Advice on common storage:

Do not store together with alkalis, reductants, metallic salts (risk of decomposition).

▼M1

Do not store together with organic solvents (risk of explosion).

Shelf-life:

24 months

6. OTHER INFORMATION

The full titles of the EN standards referenced in the ‘Use-specific mitigation measures’ sections are:

EN 16321 - Eye and face protection for occupational users

EN 374 – Protective gloves against chemicals and micro-organisms

The Council Directive referenced in the ‘Use-specific mitigation measures’ sections is: Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998[RMJ1] , p.11).

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2**7.1. Trade name(s), authorisation number and specific composition of each individual product**

Trade name(s)		Divozon 35 VT66		Market area: EU	
		Divozon 35		Market area: EU	
		Divosan BA 35 VT66		Market area: EU	
		Divosan BA 35		Market area: EU	
		Divozon 350		Market area: EU	
		Divozon 350 Bath		Market area: EU	
Authorisation number		EU-0029435-0002 1-2			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 % (w/w)

1. META SPC 3 ADMINISTRATIVE INFORMATION**1.1. Meta SPC 3 identifier**

Identifier	Meta SPC: META Divosan D
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1.2. Suffix to the authorisation number

Number	1-3
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1.3. Product type(s)

Product type(s)	PT04: Food and feed area
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▼ M1**2. META SPC 3 COMPOSITION****2.1. Qualitative and quantitative information on the composition of the meta SPC 3**

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 - 49,9 % (w/w)

2.2. Type(s) of formulation of the meta SPC 3

Formulation type(s)	SL Soluble concentrate
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

Hazard statements	H302: Harmful if swallowed. H315: Causes skin irritation. H318: Causes serious eye damage. H335: May cause respiratory irritation. H412: Harmful to aquatic life with long lasting effects. H272: May intensify fire; oxidiser.
Precautionary statements	P261: Avoid breathing vapours. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P271: Use only outdoors or in a well-ventilated area. P273: Avoid release to the environment. P280: Wear protective clothing / eye protection / face protection. P301+P312: IF SWALLOWED: Call a POISON CENTER / doctor / physician if you feel unwell. P330: Rinse mouth. P302+P352: IF ON SKIN: Wash with plenty of water/ soap. P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P312: Call a POISON CENTER/doctor/physician if you feel unwell. P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P310: Immediately call a POISON CENTER / doctor. P332+P313: If skin irritation occurs: Get medical advice. P403+P233: Store in a well-ventilated place. Keep container tightly closed. P405: Store locked up. P501: Dispose of contents in accordance with local requirements.

▼ **M1**

P501: Dispose of container in accordance with local requirements.
P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P220: Keep away from clothing or other combustible materials.
P370+P378: In case of fire: Use water to extinguish.

4. **AUTHORISED USE(S) OF THE META SPC**4.1. **Use description***Table 1***Disinfection of distribution system for drinking water by cleaning in place (CIP)**

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: fungi Development stage: no data
Field(s) of use	indoor use Disinfection of distributing and storing installations for drinking water.
Application method(s)	Method: CIP (Cleaning in place) in closed systems Detailed description: Disinfecting the interior surfaces of closed systems by CIP
Application rate(s) and frequency	Application Rate: 4,7 % (w/w) hydrogen peroxide For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, in the case of a product containing 35% (w/w) hydrogen peroxide: add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 3 hours Frequency: Daily / if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

▼ M1

4.1.1. *Use-specific instructions for use*

CIP (Cleaning in place): Clean prior to disinfection. Circulate the diluted product through the system under conditions of increased turbulence and flow velocity. After 3 hours contact time, pipelines and tanks are rinsed with water before refilled with drinking water. For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide.

For example, for a product containing 35% (w/w) hydrogen peroxide: add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

4.1.2. *Use-specific risk mitigation measures*

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent, face shield and RPE (APF = 10) during mixing and loading. See section 6 for the full titles of the EN standards.

Glove and coverall material to be specified by the authorisation holder within the product information.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH). Observe label instructions.

4.1.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

4.1.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

4.1.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

4.2. Use description

Table 2

Disinfection of non-porous hard surfaces and equipment by immersion

Product type	PT04: Food and feed area
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▼ **M1**

Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: fungi Development stage: no data
Field(s) of use	indoor use Equipment in both food and drink industries, large scale catering kitchens and large scale canteens.
Application method(s)	Method: Open system: immersion Detailed description: Manual immersion of equipment in closed baths. Automated immersion of equipment in closed baths.
Application rate(s) and frequency	Application Rate: 8,1% (w/w) hydrogen peroxide. For disinfection of bacteria, yeasts and fungi the product should be diluted to 8,1% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide: add 200 ml product to 738 ml water to achieve a dilution of 8,1% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: 60 minutes Frequency: Daily / if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

4.2.1. *Use-specific instructions for use*

For disinfection of bacteria yeasts and fungi the product should be diluted to 8,1% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide: add 200 ml product to 738 ml water to achieve a dilution of 8,1% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

Immersion: Equipment in the food and feed industry is disinfected by immersion. Pre-clean the equipment. The disinfection solution should be diluted into vats (i.e. pouring or pumping the product into vats). The equipment to be disinfected is manually or automatically placed into these vats (closed baths) and taken out after a contact time of not less than 60 minutes. After the disinfection procedure is completed, equipment is rinsed with water. The disinfection of the immersion/dipping bath should be replaced after each disinfection cycle.

▼ **M1**4.2.2. *Use-specific risk mitigation measures*

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent, face shield and RPE (APF = 10) during mixing and loading and application. Glove and coverall material to be specified by the authorisation holder within the product information. See section 6 for the full titles of the EN standards.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC. No access to the room is permitted during disinfection without wearing adequate PPE and RPE as described above.

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH). Dipping bath has to be placed in a separate room. For use only in areas inaccessible to the general public. Professional users without PPE and RPE (APF=10) are not allowed to enter the disinfection room. Keep the bath closed during disinfection, only open to load and discharge.

Observe label instructions.

4.2.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

4.2.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

4.2.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

4.3. **Use description**

Table 3

Disinfection of surfaces by cleaning in place (CIP)

Product type	PT04: Food and feed area
Where relevant, an exact description of the authorised use	-
Target organism(s) (including development stage)	Common name: Bacteria Development stage: no data Common name: Yeasts Development stage: no data Common name: fungi Development stage: no data
Field(s) of use	indoor use Disinfection of food contact inner surfaces of pipe work and tank systems in food and feed industry.

▼ **M1**

Application method(s)	Method: CIP in closed systems Detailed description: Disinfecting the interior surfaces of closed systems by Cleaning In Place (CIP).
Application rate(s) and frequency	Application Rate: 4,7% (w/w) hydrogen peroxide. For disinfection of bacteria, yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide: add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly. Number and timing of application: Contact time: at least 3 hours Frequency: Daily / if required Temperature: room temperature
Category(ies) of users	professional
Pack sizes and packaging material	HDPE bottle 1,5 litres HDPE jerry can 10, 20, 30, 60 litres HDPE drum 200 litres HDPE container 1 000 litres HDPE ISO tank 20m ³

4.3.1. *Use-specific instructions for use*

Clean prior to disinfection. The inner surfaces of pipe work and tank systems are disinfected by CIP process. For disinfection of bacteria yeasts and fungi the product should be diluted to 4,7% (w/w) hydrogen peroxide. For example, for a product containing 35% (w/w) hydrogen peroxide: add 114 ml product to 819 ml water to achieve a dilution of 4,7% (w/w) hydrogen peroxide. For products with different concentrations of hydrogen peroxide the values have to be adjusted accordingly.

The process is carried out by circulating the disinfection solution through the system under conditions of increased turbulence and flow velocity. The application is automated and a closed process. After 3 hours contact time, pipelines and tanks are rinsed with water under closed system conditions as well.

4.3.2. *Use-specific risk mitigation measures*

Wear chemical resistant goggles consistent with European Standard EN 16321 or equivalent, protective clothing chemically resistant to the biocidal product, chemical resistant gloves classified under the European Standard EN 374 or equivalent, face shield and RPE (APF =10) during mixing and loading. See section 6 for the full titles of the EN standards.

Glove and coverall material to be specified by the authorisation holder within the product information.

▼ M1

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full reference to Council Directive 98/24/EC.

Technical RMM: Local exhaust ventilation (50 %) and good standard of general ventilation (3 ACH). Observe label instructions.

4.3.3. *Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment*

No use specific first aid instructions and emergency measures to protect the environment. See general directions for use.

4.3.4. *Where specific to the use, the instructions for safe disposal of the product and its packaging*

No use specific instructions for safe disposal of the product and its packaging. See general directions for use.

4.3.5. *Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage*

No use specific instructions of storage and shelf-life of the product under normal conditions of storage. See general directions for use.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 3

5.1. Instructions for use

See use specific instructions for each use.

5.2. Risk mitigation measures

See use specific risk mitigation measures for each use.

Observe label instructions.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

First aid instructions

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing.

If symptoms: Call 112/ambulance for medical assistance.

If no symptoms: Call a POISON CENTRE or a doctor.

▼ M1***Accidental release measures***

Large spillage: Collect product in suitable containers (for example made of plastic) using appropriate equipment (for example liquid pump) for disposal. Never return spills in original containers for re-use. Keep away from flammable and incompatible substances. Rinse away any residue with plenty of water. Dispose of absorbed material in accordance with the applicable environmental regulations.

Small spillage: Dilute product with lots of water and rinse away or absorb with liquid-binding material (for example diatomaceous earth or universal binder). Pick up mechanically and collect in suitable containers. Clean contaminated surface thoroughly. Pack and label wastes like the product. Do not detach label from the delivery containers prior to disposal.

5.4. Instructions for safe disposal of the product and its packaging

At the end of the treatment, dispose of unused product and the packaging in accordance with local requirements. Used product can be flushed to municipal sewer depending on local requirements.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage***Advice on protection against fire and explosion:***

Store away from direct sunlight and heat sources.

Store away from sources of ignition - No smoking.

Store away from flammable substances.

Store away from incompatible substances.

Storage:

Temperature requirement- during storage maximum 40 °C and protect from frost.

Store in clean, dry and well- ventilated places.

Transport and store container in upright position only.

Always close container tightly after removal of product.

Avoid leakage and residues of the product on the containers.

Advice on common storage:

Do not store together with alkalis, reductants, metallic salts (risk of decomposition).

Do not store together with organic solvents (risk of explosion).

Shelf-life:

24 months

6. OTHER INFORMATION

The full titles of the EN standards referenced in the 'Use-specific mitigation measures' sections are:

▼M1

EN 16321 - Eye and face protection for occupational users

EN 374 – Protective gloves against chemicals and micro-organisms

The Council Directive referenced in the ‘Use-specific mitigation measures’ sections is: Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998[RMJ1] , p.11).

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

7.1. Trade name(s), authorisation number and specific composition of each individual product

Trade name(s)		Divosan D30		Market area: EU	
		Divosan D30 VT91		Market area: EU	
Authorisation number		EU-0029435-0003 1-3			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrogen peroxide		Active substance	7722-84-1	231-765-0	35 % (w/w)